DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#12

MAR 20 1989

Re: Ceradon
Docket Nos. 89E-0086
and 89E-0087

SOLICITOR

MAR 24 1989

U.S. PATENT & TRADEMARK OFFICE

Charles E. Van Horn, Esq.
Deputy Solicitor, Solicitor's Office
U.S. Patent and Trademark Office
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 4,161,527 and 4,241,057 filed by Takeda Chemical Industries, Ltd. under the patent term extension provisions of 35 U.S.C. 156. The human drug product claimed by the patents is Ceradon (cefotiam hydrochloride), New Drug Application (NDA) 50-601.

A review of the Food and Drug Administration's official records confirms that Ceradon was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that NDA 50-601 represents the first permitted commercial marketing or use of the active ingredient cefotiam hydrochloride.

The NDA was approved on December 30, 1988, which makes the submission of the patent term extension application on February 23, 1989 timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d) we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)

cc: Douglas P. Mueller
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